

FEB 20 2001

K 003608

Page 1 of 1

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
in Accordance with SMDA of 1990**SOVEREIGN™ BIPOLAR INSTRUMENTS**

November 21, 2000

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Lisa M. Millington, Regulatory Associate
800-258-1946 (phone)
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TRADE NAME: SOVEREIGN™ Bipolar Instruments for Gynecology

COMMON NAME: Bipolar Instrument

DEVICE CLASS: Class II

PRODUCT CODE: 85HGI

CLASSIFICATION: 884.4120
Electrocautery, Gynecologic (AND ACCESSORIES)

REVIEW PANEL: Obstetrics / Gynecology

INTENDED USE

The Sovereign Bipolar Instruments are intended to be used in bipolar tissue manipulation and coagulation in laparoscopic gynecology procedures.

DEVICE DESCRIPTION

Aesculap's Sovereign Bipolar Instruments for Gynecology are comprised of a variety of non-sterile, reusable endoscopic scissors and forceps. The modular instruments utilize standard bipolar cables (with flat plugs) connected to compatible electrosurgical generators that supply bipolar energy. The instruments may be sterilized by steam sterilization.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The Sovereign Bipolar Instruments, however, conform to the following electromedical standard: IEC 60601-2-18.

SUBSTANTIAL EQUIVALENCE

The Sovereign Bipolar Instruments for Gynecology are substantially equivalent in their intended use, material composition, labeling, design and basic operating principles to the following predicate devices:

- Aesculap Bipolar Forceps (K954652, K001330)
- Bissinger Detachable Bipolar Coagulation (K970968)
- Karl Storz Bipolar Forceps (K953809)
- Enterprise Medical Laparoscopic Scissors (K942431)
- Baxter Scissors, Grasping Forceps, Needle Holder (K940709)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 20 2001

Ms. Lisa M. Millington
Regulatory Associate
AESCULAP®, Inc.
944 Marcon Blvd.
ALLENTOWN PA 18109

Re: K003608
SOVEREIGN™ Bipolar Instruments for Gynecology
(Maryland Fixation Forceps, Micro Fixation Forceps,
Macro Fixation Forceps, and Metzenbaum Scissors)
Dated: November 21, 2000
Received: November 22, 2000
Regulatory Class: II
21 CFR §884.4120/Procode: 85 HGI

Dear Ms. Millington:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


Daniel G. Schultz, M.D.

Captain, USPHS

Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003608Device Name: **SOVEREIGN™ Bipolar Instruments for Gynecology**

Indication for Use:

The Sovereign Bipolar Instruments consist of modular, endoscopic bipolar forceps and scissors. The Sovereign Bipolar Instruments are intended to be used in bipolar tissue manipulation and coagulation in laparoscopic gynecology procedures. The forceps are not intended to be used for female sterilization procedures. (added)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 3-10-98)

David A. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003608